

REMARKS

Claims 16-25 are pending. No claims have been allowed. Claims 16-19, 24, and 25 have been amended in the manner suggested by the Examiner.

A Listing of Claims has now been provided as requested in the Office Action mailed July 6, 2005. Claims 26 and 27 have now been accounted for.

There appears to be a misunderstanding as to what the applicant's vaccine is. The paragraph bridging columns 2 and 3 disclose the vaccine that is claimed. Example 1 discloses the method for making the claimed vaccine. In step 6, the supernatant fraction containing all of the extractable intracellular proteins was mixed with the liquid phase containing extracellular proteins. In step 7, an aliquot of the mixture was analyzed by SDS gel electrophoresis to confirm that the mixture contained the three immunodominant proteins contributed by the supernatant fraction containing all of the extractable intracellular proteins. In some cases, the immunodominant proteins were cut from the gel and added to Mendoza's original vaccine (SCAV). In step 8, after visualizing the immunodominant proteins on the gel, the remainder of the mixture was precipitated with acetone and in step 9, the precipitate was resuspended in water. In step 10, the resuspended precipitate was dialyzed against water and then stored until use. The vaccine in

step 10 contains all of the extractable intracellular proteins including the three immunodominant proteins and the extracellular proteins. Thus, Example 1 discloses the method for making the vaccine in the claims.

Example 2 provides results from a vaccination therapy experiment where horses were vaccinated with the vaccine prepared as in Example 1 (page 8, lines 13-21). While the example appears to discuss the results for Mendoza's original vaccine containing the three immunodominant proteins, the Example is really discussing the results for the vaccine prepared as in Example 1. Thus, Example 2 demonstrates that the vaccine of the claims was efficacious in the same manner as Mendoza's original vaccine (SCAV) containing the three immunodominant proteins purified by gel electrophoresis as mentioned in step 7 and as disclosed in Mendoza (1995) and Mendoza (1996). Example 4 discloses that the vaccine of Example 1 was able to cure a human chronically infected with *Pythium insidiosum*.

In light of the above, the applicant's vaccine in the claims is supported by the specification and is clearly distinguishable from the vaccine disclosed in Mendoza (1995) and Mendoza (1996).

1. Claim 25 was objected to for omitting a modifier between precipitated and acetone.

The omission has been corrected.

2. Claims 16-19 and 24 were rejected under 35 U.S.C. § 112, second paragraph.

Claims 16, 17, 18, 19, and 24 have been amended in the manner suggested by the Examiner.

3. Claims 16-25 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Mendoza et al. (1996), Mendoza et al. (1992a) (IDS: AI), Mendoza et al. (1992b) (IDS: AJ), Sigma Catalogue (1992), Amicon Catalogue (1993), and Mendoza abstract (1995).

The applicant believes that the prior art does not render the instant invention obvious for the following reasons.

The applicant's vaccine as disclosed in the instant application provides a result that one with ordinary skill in the art would not expect by merely combining the intracellular proteins from the CMV and the extracellular proteins of the SCAV. As taught by Mendoza (1992a), neither the CMV nor the SCAV is able to cure chronically infected horses. Thus, one with ordinary skill in the art would have no reason to believe that a vaccine that combined all of the extractable intracellular proteins with extracellular proteins as taught by the applicant in the instant

application would produce a vaccine with curative properties not seen with either the vaccine consisting solely of intracellular proteins (CMV) or extracellular proteins (SCAV). The ability of the applicant's vaccine as disclosed in the instant application to cure chronically infected horses would not have been unexpected.

While Mendoza (1992b) discloses that antisera from a horse with pythiosis reacted with 32K, 30K, and 28K immunodominant proteins from *Pythium insidiosum*, and Mendoza (1995) and Mendoza (1996) both describe a vaccine which consisted of the SCAV with the addition of the three immunodominant proteins and which was able to cure chronically infected horses, the prior art provides no motivation to one with ordinary skill in the art to make a vaccine that combined *all* of the extractable intracellular proteins with the extracellular proteins. It is true that the three immunodominant proteins are intracellular proteins; however, while the prior art taken as a whole suggests that a vaccine which contained extracellular proteins with the three immunodominant proteins could be efficacious, the prior art also suggests that a vaccine consisting of all of the extractable intracellular proteins added to the SCAV would not produce the same result. That is because the CMV, which *inter alia* contained the three immunodominant

proteins, was unable to cure chronically infected horses. The inability of the CMV to cure chronically infected horses would suggest that the total population of intracellular proteins contained other constituents that interfered with the ability of the three immunodominant proteins to cure chronically infected horses. Therefore, to make a vaccine to cure chronically infected horses, one with ordinary skill in the art would have followed the teachings of Mendoza (1995) and Mendoza (1996) and prepared a vaccine by adding only the three immunodominant proteins to the SCAV, not by mixing all of the extractable intracellular proteins with the extracellular proteins as taught by the applicant in the instant application.

In light of the above, the Sigma Catalogue (1992) and the Amicon Catalogue (1993) in view of the above of the prior art would not have made the applicant's invention obvious. Neither catalogue contains any disclosure which would have made preparing a vaccine consisting of all of the extractable intracellular proteins with the extracellular proteins suddenly obvious when viewed in light of the above prior art.

Because the applicant's vaccine had the unexpected ability to cure chronically infected horses in light of the prior art which showed that a vaccine

containing the all of the extractable intracellular proteins lacked that ability whereas a vaccine containing the three particular immunodominant proteins, which had been purified and mixed with extracellular proteins, could cure chronically infected horses, the rejection appears to be a hindsight rejection based on the applicant's disclosure. Without the applicant's disclosure in the instant application, there would have been no reason for one skilled in the art to expect that a vaccine that contained all of the extractable intracellular proteins mixed with the extracellular proteins would cure chronically infected horses. Thus, one with ordinary skill in the art would not have been motivated to prepare a vaccine as taught by the applicant in the instant application.

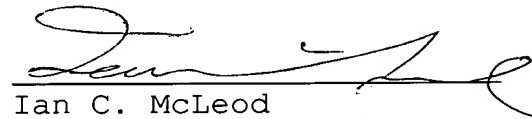
Furthermore, the prior art does not even remotely suggest the use of the claimed vaccine in humans. Because humans and horses are not evolutionarily related, it is unlikely that one of ordinary skill in the art would have considered a veterinary vaccine for use in humans. Therefore, Claims 16 and 17, which specifically call for a method for vaccinating humans, would not have been obvious over the prior art.

In light of the above, Claims 16-25 are not obvious over the prior art. Reconsideration of the

rejection is requested.

Claims 16, 17, 18, 19, 24, and 25 have been amended to place the claims in proper form for allowance. Notice of Allowance is requested.

Respectfully,

A handwritten signature in cursive script, appearing to read "Ian C. McLeod", written over a horizontal line.

Ian C. McLeod
Registration No. 20,931

McLEOD & MOYNE, P.C.
2190 Commons Parkway
Okemos, MI 48864

(517) 347-4100
Fax: (517) 347-4103